UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,077	09/29/2003	Linda Arterburn	2715.0350001/JUK/SMW	4735

91335 7590 12/30/2009
Sterne, Kessler, Goldstein & Fox P.L.L.C
1100 New York Avenue, N.W.
Washington, DC 20005

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
12/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,077	ARTERBURN ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 4, 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-7,10-21 and 23* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 4-7, 10-18, 20, 21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/4/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed November 4, 2009 have been received and entered into the application.

Response to Arguments

Applicants' arguments filed November 4, 2009 have been fully considered but they are not persuasive. Applicants argue that Rubin emphasizes the use of "free fatty acid" EPA or DHA or mixtures thereof and not the triglyceride form. Therefore, one of skill in the art would not have looked to the triglyceride forms of these fatty acids to treat diabetes mellitus. This is not persuasive because Applicants attention is drawn to column 5 of Rubin under the detailed description of the invention, second full paragraph, where it teaches that the EPA and/or DHA **need not** be administered as **the free fatty acids per se**. Rubin further teaches that the effects of EPA and DHA in general in the treatment of diabetes has to do with metabolism of leukotrienes (column 4, lines 55-59). Therefore, Rubin teaches the composition comprising DHA and/or EPA in general is useful for the treatment of diabetes mellitus. Further, disclosed examples and preferred embodiments in Rubin of fatty acids of DHA and/or EPA do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). The mere fact that the preferred embodiment is free fatty acids of DHA and/or EPA does not teach away from the broad disclosure which discloses, as

indicated above that a composition comprising DHA and/or EPA is useful for the treatment of diabetes because they affect the metabolism of leukotrienes. Applicants argue that Rubin does not disclose the measuring of HbA1c in the blood of an individual; the administration of about 200mg to about 1.5g DHA in triglyceride form; or the co-administration of a second pharmaceutical. This is not persuasive because that HbA1c is a useful as an index of hyperglycemic stress in diabetic patients is well known in view of Remmereit et al. Remmereit et al teach HbA1c is elevated in patients with poorly managed diabetes and teach how to determine HbA1c level in diabetic patients. One would have been motivated to measure the HbA1c level in diabetic patients disclosed by Rubin prior to or during the antidiabetic treatment in order to provide accurate therapeutic amounts of DHA/EPA as needed. Further, the effective amount of EPA and/or DHA for the treatment of diabetes as being at least 0.5gm (500mg) is well taught by Rubin. This amount is within Applicants range of 200mg to 1.5gm; and the DHA-rich oils with a preponderance of DHA-containing mixed triglycerides are well known by Katz et al. Accordingly, one of ordinary skill in the art would be motivated to employ DHA-rich oils taught by Katz et al. for the treatment of diabetes in order to achieve the beneficial effect of DHA in the diabetic patients disclosed by Rubin. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2, 4-7, 10-18, 20, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin (U.S. Patent No. 5,034,415) of record in view of Katz et al. (U.S.Patent No. 5,925,669) and further in view of Remmereit et al. (U.S.Patent No. 6,440,931 B1) of record and further in view of Harris et al. (1997) of record.

Rubin teaches that EPA **or** DHA **or** mixtures thereof are useful for treating diabetes mellitus. (claim 1, column 5, lines 15-35). Rubin teaches the composition comprising DHA and EPA can replace butter and/or ordinary margarine or cooking oils. (column 5, lines 61-68). Rubin teaches that EPA and/or DHA composition can be administered at least 0.5gram, and preferably from 1.5 to 5 gram per day. (column 5, lines 25-30). Rubin teaches treatment of patients suffering from diabetes mellitus with sardine oil containing **DHA in the triglyceride form**, and with sardine oil after hydrolysis of the acids and removal of the glycerin. The treatment of adult diabetic in the table on column 9 was administered fish oil comprising triglyceride.

Rubin does not teach the employment of DHA is in the form of a triglyceride oil **substantially free of EPA**, glycosylated hemoglobin (HbA1c) measurement in blood, combinations with the antidiabetic set forth in claim 5, prediabetic patients, chronic therapy, amounts of DHA compared with other fatty acids set forth in claim 23 and the specific patient population set forth in claims 10-16 and dosing schedule set forth in claims 17 and 18.

Katz et al. teach that recently new natural sources of DHA-rich oils, with a preponderance of DHA-containing mixed triglycerides have been identified and developed including oils from algae and algae-like microorganisms that provide odorless oils that contain up to 50% DHA, are free of EPA and essentially no other polyunsaturated fatty acids. (column 1, lines 55-67).

Remmereit et al. teach that HbA1c (glycosylated hemoglobin) is a useful as an index of hyperglycemic stress, and is elevated in patients with poorly managed diabetes. Remmereit et al. teach that the glycosylation of HbA1c is a non-enzymatic, post-translational event linked to elevated levels of glucose in blood. Remmereit et al. teach that HbA1c levels may be determined as is known in the art by HPLC. (column 6, lines 34-42). Remmereit et al. teach that diabetes mellitus is a chronic metabolic disorder characterized by a high concentration of glucose in blood which is a result of insulin deficiency and/or insulin resistance. (column 1, lines 15-20). Remmereit et al. teach that insulin is the main form of treatment of Type I diabetes. Remmereit et al. teach that Type II diabetes can be treated with various oral anti-hyperglycemic agents like biguanidines (e.g., metformin), sulphonylurea compounds such as tolbutamide, chlorpropamide, glipizide and glibenclamide, and acarbose (i.e. an alpha-glucosidase inhibitor). (column 1, lines 24-36).

Harris et al. teach that comparison of diabetes diagnostic categories in the U.S. Population including impaired fasting glucose defined as fasting plasma glucose of 110-125mg/dl and mean HbA1c 7.07. (title, page 1859, right hand side, first paragraph, Table 2).

It would have been obvious to one of ordinary skill in the art to measure blood glucose level in diabetic patients of Rubin by measuring glycosylated hemoglobin (HbA1c) decrease because Rubin teaches that DHA composition is effective for treating diabetes and because Remmereit et al. teach HbA1c is elevated in patients with poorly managed diabetes and the determination of HbA1c level is well known in the art in view of Remmereit et al. One would have been motivated to measure decrease in HbA1c in diabetic patients disclosed by Rubin in order to determine if the dosing adjustment of DHA/EPA composition in antidiabetic therapy is necessary. Further, it would have been obvious to one of ordinary skill in the art to combine other antidiabetic agents such as biguanidines (e.g., metformin), sulphonylurea compounds such as tolbutamide, chlorpropamide, glipizide and glibenclamide, and acarbose (i.e. an alpha-glucosidase inhibitor) to Rubin's composition in order to achieve at least an additive antidiabetic effect. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). It would have been obvious to one of ordinary skill in the art to employ Rubin's composition to treat diabetics chronically because that diabetes mellitus is a chronic disorder in view of Remmereit et al.

With regard to the employment of DHA in the form of a triglyceride oil that is substantially free of EPA, such is obvious because Rubin teaches that DHA or EPA is effective for the treatment of diabetes. Rubin illustrates the administration of DHA in the form of triglyceride oil to a diabetic patient while Katz teaches new odorless natural sources of DHA-rich oils, with preponderance of DHA-containing free of EPA is well

kwon in the art. One of ordinary skill in the art would be motivated to employ new natural source of DHA-rich oils in the diabetic patients disclosed by Rubin in order to achieve an expected benefit of treating diabetic patients taught by Rubin with preponderance of odorless DHA-rich oils reported by Katz et al.

It would have been obvious to one of ordinary skill in the art to employ DHA-rich oils composition taught by Rubin as modified by Katz and Remmereit et al. to a patient exhibiting fasting glucose between about 110 to about 125mg/dl and the criteria set forth in claims 10-18 because a fasting plasma glucose of 110-125mg/dl is defined as an impaired fasting glucose within the diagnostic classes taught by Harris et al. and because the criteria set forth in claims 10-16 are obvious the diagnostic categories within the teaching by Harris et al. and the variations within any one or more of the risk factors that would be reasonably expected to be differ from patient to patient. Further, the dosing schedule or the frequency of administration of the antidiabetic to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Jmk
December 23, 2009